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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,125	08/14/2001	Susan Hand-Zimmermann	210121.544	9404

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EXAMINER
UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/930,125	Applicant(s) Hand-Zimmermann et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 29, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above, claim(s) *1 and 6-12* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-5* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Election filed May 29, 2003 (Paper No. 10) in response to the Office Action of November 29, 3002 (Paper No. 5) is acknowledged and has been entered. Claims 1-12 are pending in the application and Claims 1 and 6-12 have been withdrawn from further consideration by the examiner under 37 CAR 1.142(b) as being drawn to non-elected inventions. Claims 2-5 are currently under prosecution.

2. The response (Paper No. 8) to the restriction requirement of November 28, 2002 has been received. Applicant has elected Group II, claims 2-5 for examination. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a).

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76. Further, the signatures provided are not dated.

Specification

4 The disclosure is objected to because of the following informalities:

(A) The specification on page 1 should be amended to reflect the status of the parent applications. Further, when establishing priority to provisional applications, the appropriate form is as follows:

"This application claims benefit to provision application **********, filed **, now abandoned." Appropriate correction is required.

(B) The use of the trademarks such as "Tween 20" disclosed on page 78 of the specification have been noted in this application. They should be capitalized wherever they appear and be accompanied by generic terminology. The application is replete with trademarks that are either not capitalized or are not accompanied by generic language. Examiner has made an effort to identify these informalities but applicant must carefully review the specification to identify and indicate where these informalities may be found.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

5. Claim 3 is objected to because it recites non-elected limitations. Appropriate correction is required.

Double Patenting

6. The non-statutory double patenting rejection, whether of the obviousness type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a policy relected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 438, 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed b the assignee must fully comply with 37 CFR 3.73(b)

7. Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1 and 2 of US Patent No. 6,075,122. It is noted that although the claims are drawn to a isolated polypeptide effective to elicit an immune response, this limitation is viewed as a recitation of intended use and therefore is not given weight in comparing the claim with the patented case. Claims 2 and 3 read on the ingredients *per se*, which are a polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO:3 and a pharmaceutically acceptable carrier.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the patented case and would have been obvious in view of the copending claims which have all of the characteristics of a polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO 3. Further, it would have been prima facie obvious to make a composition of the polypeptide because Johnstone and Thorpe (Immunochemistry in Practice, 2nd Ed., 1987, Blackwell Scientific Publications, Oxford, pages 49-50) teach that it was common practice in the art at the time of applicant's invention to formulate compositions of proteins and PBS, which is considered to be a pharmaceutically acceptable, p. 49 and 50.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 2-5 are rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,075,122.

The claims are drawn to an isolated polypeptide composition effective for eliciting an immune response, said polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO:3, a pharmaceutical composition comprising said polypeptide in combination with a pharmaceutically acceptable carrier, said composition further comprising an immunostimulant, wherein said immunostimulant comprises an adjuvant.

US Patent No.6,075,122 teaches SEQ ID NO:69, (see Figure 1) which is an isolated polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO:3 (see sequence search report us-09-930-125-3.rai, result 4). US Patent No.6,075,122 specifically teaches that SEQ ID NO:69 may not be used alone for immunization but teaches that the HER-2/neu peptide, which functions as an antigen, and includes SEQ NO. 69, may be used for immunization when the immunization composition includes other components such as a vehicle for antigen delivery and immunostimulatory substances designed to enhance the protein's immunogenicity. Examples of pharmaceutically acceptable vehicles for antigen delivery include aluminum salts, water-in-oil emulsions, biodegradable oil vehicles, oil-in-water emulsions biodegradable microcapsules and liposomes and examples of immunostimulatory substances include adjuvants. The composition is immunogenic not only for T cells but also stimulates B-cells to produce antibodies capable of recognizing HER-2/neu protein, further, when a peptide is used without additional

sequences, it is desirable to couple the peptide hapten to a carrier substance such as KLH (cols 15-16). All of the limitations of the claims are met.

10. Claims 2-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 5,801,005, IDS item AA.

The claims are drawn to an isolated polypeptide composition effective for eliciting an immune response, said polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO:3, a pharmaceutical composition comprising said polypeptide in combination with a pharmaceutically acceptable carrier, said composition further comprising an immunostimulant, wherein said immunostimulant comprises an adjuvant.

US Patent No. 5,801,005 teaches SEQ ID NO:69, (see Figure 1) which is an isolated polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO:3 (see sequence search report us-09-930-125-3.rai, result 1). US Patent No. 5,801,005 specifically teaches that SEQ ID NO:69 may not be used alone for immunization but teaches that a the HER-2/neu peptide which functions as an antigen, and includes SEQ NO. 69, may be used for immunization when the immunization composition includes other components such as a vehicle for antigen delivery and immunostimulatory substances designed to enhance the protein's immunogenicity. Examples of pharmaceutically acceptable vehicles for antigen delivery include aluminum salts, water-in-oil emulsions, biodegradable oil vehicles, oil-in-water emulsions biodegradable microcapsules and liposomes and examples of immunostimulatory substances include adjuvants. The composition is immunogenic not only for T cells but also stimulates B-cells to produce antibodies capable of

recognizing HER-2/neu protein, further, when a peptide is used without additional sequences, it is desirable to couple the peptide hapten to a carrier substance such as KLH (col 14, lines 5-42). All of the limitations of the claims are met.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

12. Claims 2-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Slamon et al (Science, 1989, 707-244, IDS item DH) or Yamamoto et al, Nature, 1986, 319:230-234) or Coussens et al (Science, 1985, 230:1132-1139)in view of Harlow and Lane, (Antibodies, A Laboratory Manual, 1988, Cold Spring Harbor Laboratory, New York ([see pages 96 and 97]) and Johnstone and Thorpe (Immunochemistry in Practice, 2nd Ed., 1987, Blackwell Scientific Publications, Oxford, pages 49-50).

The claims are drawn to an isolated polypeptide composition effective for eliciting an immune response, said polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO:3, a pharmaceutical composition comprising said polypeptide in combination with a pharmaceutically acceptable carrier, said composition further comprising an immunostimulant, wherein said immunostimulant comprises an adjuvant.

As drawn to claim 2, Slamon et al teach an isolated polypeptide, HER-2/neu protein comprising an amino acid sequence consisting essentially of SEQ ID NO:3(see Figure 1, p. 244), but do not teach a composition comprising said polypeptide, a pharmaceutical composition for eliciting an immune response comprising said polypeptide, said pharmaceutical composition comprising a pharmaceutically acceptable carrier, an immunostimulant.

As drawn to claim 2, Yamamoto et al teach an isolated polypeptide, HER-2/neu protein comprising an amino acid sequence consisting essentially of SEQ ID NO:3 (see Figure 4, p. 233), but do not teach a composition comprising said polypeptide, a pharmaceutical composition for eliciting an immune response

comprising said polypeptide, said pharmaceutical composition comprising a pharmaceutically acceptable carrier, an immunostimulant.

As drawn to claim 2, Coussens et al teach an isolated polypeptide, HER-2/neu protein comprising an amino acid sequence consisting essentially of SEQ ID NO:3 (see Figure 3, p. 1135), but do not teach a composition comprising said polypeptide, a pharmaceutical composition for eliciting an immune response comprising said polypeptide, said pharmaceutical composition comprising a pharmaceutically acceptable carrier, an immunostimulant.

Harlow and Lane teach that adjuvants are essential to induce a strong antibody response to soluble antigens (p 96, para 1). The overall effect of adjuvants is dramatic and their importance cannot be overemphasized. A much smaller dose of antigen can be used and antibody responses are more persistent. The nonspecific activation of the immune response often can spell the difference between success and failure in obtaining an immune response. Adjuvants should always be used for the first injections unless there is some very specific reason to avoid this.

Johnstone and Thorpe teach that it was common practice in the art at the time of applicant's invention to formulate compositions of proteins and PBS, which is considered to be a pharmaceutically acceptable carrier.

As drawn Slamon et al, although no sequence is taught for the isolated HER-2/neu protein, given that the protein is isolated from a human source, the claimed polypeptide appears to be the same as the prior art polypeptide. However, the office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art

does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed polypeptides are structurally and functionally different than those taught by the prior art and to establish patentable differences. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

As drawn to claims 2-5, it would have been *prima facie* obvious at the time the invention was made to have made a pharmaceutical composition comprising the polypeptide of Slamon et al or Coussens et al or Yamamoto et al comprising an amino acid sequence consisting essentially of SEQ ID NO:3, comprising a pharmaceutically acceptable carrier, an immunostimulant, an adjuvant because the Board of Patent Appeals and Interferences has taken the position that once an antigen has been isolated, the manufacture of antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990). Since the manufacture of antibodies conventionally requires administration of the antigen to an animal in a pharmaceutical composition, a pharmaceutical composition comprising said antigen is *prima facie* obvious. Especially in view of the teachings of Johnstone and Thorpe who teach that it was common practice in the art at the time of applicant's invention to formulate compositions of proteins and PBS, which is considered to be a pharmaceutically acceptable carrier. In addition it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, and one would be motivated to include an adjuvant in the composition

because Harlow and Lane teach that adjuvants are essential to induce a strong antibody response to soluble antigens. The overall effect of adjuvants is dramatic and their importance cannot be overemphasized. A much smaller dose of antigen can be used and antibody responses are more persistent. The nonspecific activation of the immune response often can spell the difference between success and failure in obtaining an immune response. Adjuvants should always be used for the first injections unless there is some very specific reason to avoid this.

13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

SUSAN UNGAR, PHD
PRIMARY EXAMINER

Susan Ungar
Primary Patent Examiner
August 1, 2003